Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte LARRY K. THOMAS

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Appeal No. 1997-2087
Application No. 08/203,837

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ON BRIEF

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Before WILLIAM F. SMITH, SCHEINER, and MILLS, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 4, 6, 8 through 11, 15, 18, 19, 21 through 23, 25, 26, and 28, all the claims pending in the application. Claims 2, 3, 5, 7, 13, 16, and 17 were cancelled in the amendment filed September 24, 1993 (Paper No. 4). Claims 1, 12, 14, 20, 24, and 27 were cancelled in the amendment filed February 7, 1994 (Paper No. 6), entered in accordance with appellant's instructions filed February 28, 1994 (Paper No. 10).

Claims 15 and 25 are representative of the claims on appeal:

15. A method for disinfecting a contact lens comprising:

contacting a contact lens with a liquid medium initially containing an effective contact lens disinfecting amount of hydrogen peroxide in the presence of a composition comprising a cellulose decomposing enzyme component, a cleaning enzyme component and a hydrogen peroxide destroying component, said composition being structured so that said cellulose decomposing enzyme component is released in said liquid medium before said hydrogen peroxide destroying component is released in said liquid medium and said cleaning enzyme component is released in said liquid medium after said contact lens is disinfected, said cellulose decomposing enzyme component being present in an amount effective to render acanthamoeba cysts present in said liquid medium more susceptible to be killed by hydrogen peroxide in said liquid medium than by hydrogen peroxide in a substantially identical liquid medium in the absence of said cellulose decomposing enzyme component, said liquid enzyme component is present in an amount effective to remove the protein deposits on said contact lens prior to said contacting and the protein deposits formed on said contact lens during said contacting from said cellulose decomposing enzyme component from said contact lens, and said hydrogen peroxide destroying component is present in an amount effective to destroy all the hydrogen peroxide contained in said liquid medium, said contacting being effective to disinfect said contact lens, to form protein deposits from said cellulose decomposing enzyme on said contact lens and to remove protein deposits present on said contact lens prior to said contacting and protein deposits formed on said contact lens during said contacting from said cellulose decomposing enzyme component from said contact lens.

25. A composition comprising a cellulose decomposing enzyme component, a hydrogen peroxide destroying component, an amount of a cleaning enzyme component effective to remove the protein deposits from a contact lens present in a liquid medium in which said cleaning enzyme component is released, the protein deposits including the protein deposits present on said contact lens prior to said contact lens being present in the liquid medium and the protein deposits formed on said contact lens from said cellulose decomposing enzyme component, and a delayed release component, said composition being a solid and structured so that said cellulose decomposing enzyme component is released in said liquid medium before said hydrogen peroxide destroying component is released in said liquid medium and said cleaning enzyme component is released in said liquid medium at substantially the same time said hydrogen peroxide destroying component is released in said liquid medium, said cellulose decomposing enzyme component being present in an amount effective to render acanthamoeba cysts present in

said liquid medium more susceptible to being killed by hydrogen peroxide in said liquid medium than by hydrogen peroxide in a substantially identical liquid medium in the absence of said cellulose decomposing enzyme component and to form protein deposits from said cellulose decomposing enzyme component in the presence of hydrogen peroxide on said contact lens, said hydrogen peroxide destroying component being present in an amount effective to destroy all the hydrogen peroxide contained in said liquid medium, and said delayed release component being present in an amount effective to delay the release in said liquid medium of said hydrogen peroxide destroying component for a sufficient time to allow a contact lens introduced into said liquid medium at substantially the same time as said composition to be disinfected.

The references relied upon by the examiner are:

Kaspar et al. (Kaspar)	4,568,517	Feb. 4, 1986
Huth et al. (Huth)	4,670,178	June 2, 1987
Kruse et al. (Kruse)	4,767,559	Aug. 30, 1988

Izumi et al. (Izumi), “The efficacy of disinfection system using hydrogen peroxide against acanthamoeba,” Journal of the Japanese Contact Lens Soc., Vol. 33, No. 4, pp. 282-86 (1991)

Grounds of Rejections

Claims 4, 6, 8 through 11, 15, 18, 19, 21 through 23, 25, 26, and 28 stand rejected under 35 U.S.C. § 103. As evidence of obviousness, the examiner relies upon Kruse, Kaspar, Huth and Izumi.

We reverse.

Background

The present invention is directed to compositions and methods for disinfecting a contact lens (specification, page 1). Specifically, the present invention relates to compositions and methods "useful to facilitate the action of hydrogen peroxide in

disinfecting contact lenses and in destroying residual hydrogen peroxide present in a liquid aqueous medium containing a contact lens which has been disinfected by the action of hydrogen peroxide" (Id.)

The composition comprises a cellulose decomposing enzyme component (CDEC) and a hydrogen peroxide destroying component (HPDC) (specification, page 4) separated by a delayed release component, which can be in the form of a coating (specification, page 15). The function of the CDEC is to "enhance the killing action of hydrogen peroxide against hydrogen peroxide-resistant microorganisms, preferably acanthamoeba cysts" (specification, page 7).

In addition, the claimed composition comprises a cleaning enzyme component useful to remove proteinaceous deposit material from the contact lens resulting from the CDEC (specification, page 9). The claimed composition also requires the composition to be "a solid and structured" in a way to allow for dissolution of each component in a particular sequence (Appendix A, claim 25, line 10). This structure includes a core that contains the HPDC and the cleaning enzyme component; a delayed release layer covering the core and the CDEC formed over the delayed release layer (specification, page 9). Note that, alternatively, the cleaning enzyme component may be provided as a coating directly adjacent to the core (Id.).

The method of the present invention comprises contacting a contact lens with a liquid medium initially containing an effective contact lens disinfecting amount of hydrogen peroxide in the presence of the claimed structured composition (specification, page 17).

Thus, the CDEC is first released in the liquid medium (specification, page 7). After the contact lens is disinfected, the HPDC and the cleaning enzyme component are released to destroy all the hydrogen peroxide contained in said liquid medium and to remove the protein deposits on said contact lens, respectively (specification, page 17).

THE REJECTION UNDER 35 U.S.C. § 103

The examiner has rejected all the claims on appeal as being obvious over Kruse, Kaspar, Huth and Izumi.

Kruse discloses a solid composition for disinfecting contact lenses comprising the structure of a core layer containing a neutralizing agent which neutralizes a disinfecting agent, a time release coating and an outer layer containing the disinfecting agent (col. 2, lines 15-26). The disinfecting agent is preferably one that supplies hydrogen peroxide (col. 2, lines 36-40). The neutralizing agent can include ascorbic acid and catalase (col. 3, lines 30-36). The time release layer can be made of polyvinyl alcohol, polyvinylpyrrolidone and other materials (col. 4, lines 20-29). Kruse also discloses that the active ingredients are released in a desired sequence (reverse sequence of manufacturing) (col. 2, lines 28-30).

Kaspar discloses a solid composition for disinfecting contact lenses comprising the structure of a core layer containing a hydrogen peroxide neutralizing agent and a time release coating (col. 2, lines 25-44). The neutralizing agent can include ascorbic acid and catalase (col. 4, lines 29, 44). The time release layer can be made of cellulose based materials, polyvinyl alcohols, and other materials (col. 5, line 62 to col. 6, line 4). Kaspar

also discloses that the active ingredients are released in a desired sequence when placed in a liquid medium containing hydrogen peroxide (col. 2, lines 16-44).

Both Kruse and Kaspar provide the basic structure of a core layer with a neutralizing agent encapsulated by a time release layer and the basic concept of dissolving the components of the solid composition in a particular sequence. However, neither of these references suggest providing an outer layer containing a cellulose decomposing enzyme component (CDEC) over the time release layer or providing a cleaning enzyme component in connection with the core layer of neutralizing agent. The examiner seeks to rectify these deficiencies with the teachings of Huth and Izumi.

Huth is directed to a process for cleaning and disinfecting contact lenses with a "solution containing a mixture of peroxide and peroxide-active enzymes" (col. 1, lines 7-11). Huth acknowledges the problem of proteinaceous buildup on contact lenses (col. 1, line 66 to col. 2, line 19). Huth addresses this problem by providing a solution of peroxide for disinfecting combined with a cleaning enzyme (col. 3, lines 16-20). The examiner relies on Huth to disclose "that it is conventional to use enzymes to remove proteinaceous build-up on contact lenses which act to irritate the eyes' of the wearer" (Examiner's Answer, page 5).

Izumi is directed to a contact lens disinfecting system that employs a lysozyme (chitin or cellulose decomposing enzyme component) combined with hydrogen peroxide to

remove cysts (Abstract). This combination is reported to kill cysts of Acanthamoeba castellani more effectively.

The examiner states that it would have been obvious to combine these references and arrive at appellant's invention because

> the practitioner would be aware that the lysozyme 1) would potentiate the activity of the hydrogen peroxide in destroying Acanthamoeba cysts per the disclosure of Izumi et al. and 2) when lysozyme was included in the composition, [sic, it] would need to be separated from the cleaning enzyme component until after it has had its disinfecting effect because the cleaning enzyme component would inactivate the lysozyme (Examiner's Answer, paragraph bridging pages 6 and 7).

Upon consideration of the entire record before us, we cannot sustain the examiner's rejection.

DISCUSSION

Patentability of a claim under 35 U.S.C. § 103 must be premised upon considering the subject matter of a claim "as a whole." As recently stated in Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996) (citation omitted): "It is well-established that before a conclusion of obviousness may be made based on a combination of references, there must have been a reason, suggestion, or motivation to lead an inventor to combine those references."

The nature of the problem which persisted in the art, and the inventor's solution, are factors to be considered in determining whether the invention would have been obvious to a person of ordinary skill in that art. Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549,

1556, 225 USPQ 26, 31 (Fed. Cir. 1985). It is part of the "subject matter as a whole" which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103. In re Nomiya, 509 F.2d 566, 184 USPQ 607 (CCPA 1975). It is rare that one factor will control the obviousness conclusion, and all evidence should be taken into consideration when making such a determination.

Appellant argues that he discovered the problem that the CDEC "disadvantageously forms protein deposits" on the contact lens in the presence of hydrogen peroxide (Appeal Brief, page 11). Appellant further argues that the discovery of the problem led to the solution of including a cleaning enzyme component "in an amount effective to remove both the protein deposits previously on the contact lens and the protein deposits formed from the CDEC" in the claimed invention (Appeal Brief, page 5). In this context, appellant also argues extensively that there is no motivation to combine the references in a manner that will lead to the claimed invention because the prior art was not aware of the problem discovered by appellant (Appeal Brief, page 13).

On the other hand, the examiner is of the opinion that the "Appellant's discovery of the problem is immaterial because Appellant's method of addressing the problem is not patentable" (Examiner's Answer, page 14). Further, the examiner states that the components of the claimed invention "are well known in the prior art to be used either separately or in various combinations for the purpose of disinfecting and cleaning a contact lens" (Examiner's Answer, page 9). From this, the examiner concludes that "[t]he

idea of combining these components flows logically from their having been individually taught in the prior art" (Id.). The examiner additionally argues that "[t]he motivation to structure the components is also clear from a reading of the prior art taken as a whole" (Examiner's Answer, page 10). The examiner supports this contention by relying on the individual teachings of the cited references and the "awareness" of the practitioner in the art (Examiner's Answer, page 15).

We disagree. A review of appellant's claims indicates that the claimed composition and method require a distinctive and particular structure that will allow the active ingredients to be released in a specific sequence. The examiner has pointed to no evidence that would lead a person of ordinary skill to combine the teachings of the cited references in a manner that yields the claimed structure (claim 25) and method (claim 15).

It is true that Kruse and Kaspar provide the basic structure of a core layer with a neutralizing agent encapsulated by a time release layer and the basic method of dissolving the components of the solid composition in a particular sequence. But, neither of the references suggests the addition of CDEC as the outermost layer and a cleaning enzyme component to the core layer for the purpose of removing protein deposits formed from the CDEC. We note that Huth and Izumi may suggest the desirability of adding these components in a contact lens cleaning/disinfecting solution. However, the examiner points to no basis in any of the references that would lead a person of ordinary skill in the art to assemble the components in a structure as claimed or use them in the order claimed.

The initial burden of establishing unpatentability rests on the examiner, In re Oetiker,

977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). To establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant. See In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). The motivation, suggestion or teaching to modify a reference may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. See Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). In re Rouffet, 149 F.3d 1350, 1355-56, 47 USPQ2d 1453, 1456 (Fed. Cir.1998). Broad conclusory statements standing alone are not "evidence." Dembiczak, Id. However, when the high level of skill in the art provides the necessary motivation, our appellate reviewing court has instructed that such reliance must be accompanied by an explanation of "what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination."
In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1458 (Fed. Cir.1998).

The examiner attempts to provide an explanation or motivation based on the individual teachings of the cited references, relying on the "awareness" of the practitioner (Examiner's Answer, paragraph bridging pages 6 and 7 and paragraph bridging pages 14 and 15). However, we do not find that the examiner has provided evidence of a "specific understanding or technological principle within [that] knowledge" that "would have

suggested the combination," such as a recognition in the prior art of the problem solved by appellants or a suggestion of a structural solution to this problem. Id. Absent evidence of such understanding or principle in the prior art, the examiner's arguments remain unsupported and, thus, the examiner has not established a prima facie case of obviousness. Consequently, we reverse.

CONCLUSION

The examiner's decision, rejecting claims 4, 6, 8 through 11, 15, 18, 19, 21 through 23, 25, 26, and 28 under 35 U.S.C. § 103 is reversed.

REVERSED

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William F. Smith	)
Administrative Patent Judge	)
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	) BOARD OF PATENT
Toni R. Scheiner	)
Administrative Patent Judge	) APPEALS AND
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	) INTERFERENCES
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Demetra J. Mills	)
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